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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,418	07/24/2007	Steven Jungles	11808-045-999/120024-045	4565
86973	7590	04/27/2011		
Jones Day 222 East 41st Street New York, NY 10017-6702			EXAMINER ROGERS, JAMES WILLIAM	
			ART UNIT	PAPER NUMBER
			1618	
			MAIL DATE	DELIVERY MODE
			04/27/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/563,418	Applicant(s) JUNGLES ET AL.	
	Examiner JAMES ROGERS	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 49-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/12/2011</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 49,52,56,63 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moser et al. (US 7,727,987, cited IDS filed 01/12/2011). This new rejection was necessitated by applicants new IDS filed 01/12/2011.

Moser teaches pharmaceutical tablets comprising crystalline forms of (6R)-L-Erythro-Tetrahydrobiopterin dihydro-chloride (BH₄), including crystalline polymorph form B useful in the treatment of neurological disorders. See claims 9-12 and col 19 lines 32-35. The pharmaceutical tablet could further comprise an antioxidant such as vitamin C (ascorbic acid) and excipients such as dicalcium phosphate. See claims 17-20 and col 18 lines 18-19 and lines 51-52.

Moser while teaching the combination of applicants claimed polymorph B and antioxidant ascorbic acid, is silent on the amounts of each ingredient relative to one another and therefore does not teach applicants claimed ratio.

However, the percentage or the ratio of specific ingredients in this composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of antioxidant needed to inhibit oxidation of BH₄. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention. It is well-established that merely selecting proportions and ranges is not patentable absent a showing of criticality. *In re Becket*, 33 USPQ 33; *In re Russell*, 169 USPQ 426.

Claims 49,51-53,55-56,58-60,62-63 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moser et al. (US 7,727,987) in view of Dietrich (US 20040058896 A1, cited applicants IDS filed 12/15/2010). This new rejection was necessitated by applicants new IDS filed 01/12/2011.

Moser is cited above. Moser does not teach the claimed excipients of crospovidone, D-mannitol and sodium stearyl fumarate.

However from the disclosure of Dietrich these excipients were well known to be useful excipients in rapid release tablets useful in delivering drugs such as BH4. See [0229],[0425], [0438],[0487]. Dietrich teaches that crospovidone is an acceptable distenegrant, mannitol is a suitable basic filler and sodium stearyl fumarate is a suitable lubricant.

Since the references are related to the same filed of endeavor, tablet formulations one of ordinary skill in the art would have a high expectation of success in adding the excipients of Dietrich to the tablet formulation of Moser. The reason to add such excipients would be to provide an immediate release tablet for delivery of polymorph B form of BH4 for a subject in need of rapid treatment for a condition treatable by BH4 such as a neurological condition. Thus the claimed invention would have been *prima facie* obvious since all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Claims 49- 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moser et al. (US 7,727,987) in view of Dietrich (US 20040058896 A1, cited applicants IDS filed 12/15/2010) in view of Toyosaki et al. (J. Agric. Food. Chem. 1989, 37, 286-289). This new rejection was necessitated by applicants new IDS filed 01/12/2011.

The combination of Moser and Dietrich is disclosed above. Moser while teaching the genus of antioxidant vitamins does not describe the use of vitamin B₂, riboflavin.

Toyosaki is used only for the disclosure within that riboflavin was a vitamin that provided an antioxidant effect. See abstract.

Since Moser teaches the use of antioxidant vitamins in general one of ordinary skill in the art would have a high expectation of success in using the vitamin riboflavin in the composition as an antioxidant. An obviousness rejection based on similarity in chemical structure and function entails the reason for one of ordinary skill in the art to make or use a claimed compound, in the expectation that compounds similar in structure will have similar properties.

Conclusion

No claims are allowed at this time.

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on [1] prompted the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy's set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is

Art Unit: 1618

filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/J. R./
Examiner, Art Unit 1618

/MICHAEL G. HARTLEY/
Supervisory Patent Examiner, Art Unit 1618